III. REMARKS/ARGUMENTS

Claims 6-10, 13-16 and 20-23 are pending. Claim 13 has been amended. Applicants respectfully submit that no new matter has been added by virtue of this amendment.

A. Rejection Under 35 U.S.C. § 112

In the Office Action, the Examiner maintained her rejection of claim 13 under 35 U.S.C. § 112 second paragraph as being indefinite. The Examiner stated that the phrase "protein derived materials" is "vague and indefinite." Although Applicants disagree with this rejection, this phrase has been deleted from claim 13. Therefore, the Examiner's § 112 rejection should be removed.

B. Rejection Under 35 U.S.C. § 102

In the Office Action, the Examiner maintained her rejection of claims 6-7, 9 and 13-16 under 35 U.S.C. § 102(e) as being unpatentable over Paradissis, et al. (5,133,974). The Examiner indicated that Applicants' argument with regard to the coated bead formulations of the Paradissis reference being different than the matrix formulations of the present invention was not persuasive. In support of her position, the Examiner respectfully pointed out that "Pharmacy Review teaches controlled-release an extended release formulations as synonymous." The Examiner further relied on the doctrine of inherency and stated that "since Paradissis et al. teach the exact same formulations for treating pain as that recited in the instant claims, they must have the same properties."

In response, Applicants respectfully submit that the previous arguments were not directed towards distinguishing the present invention and the Paradissis reference by virtue of a distinction between controlled-release and extended-release. Rather, the distinction argued in the previous response is that the claims of the present invention recite that the opioid is dispersed in a controlled-release matrix, whereas in the dosage form described in the Paradissis reference, the drug is applied to an inert core and coated with a dissolution modifying system to provide for controlled release.

In the response filed September 29, 2003, it was argued that it is known in the art that the term matrix as used in the present claims means that the opioid analgesic is

interdispersed in a material which provides for the controlled release of the opioid. Applicants supported this position by submitting a copy of "Pharmacy Review", page 53 (attached as Exhibit C), which provides that "the most common method of preparation [of a matrix] is mixing of the drug with the matrix material followed by compression of the material into tablets". In sharp contrast, the controlled release formulation described in the Paradissis reference comprises immediate release inert core coated with drug and further coated with a dissolution modifying system (See: col. 3, lines 21-28). Coated bead formulations are separately discussed on page 53 of "Pharmacy Review".

It is respectfully submitted that coated bead formulations (as exemplified by the Paradissis reference) are recognized to one skilled in the art as different than matrix formulations, as evidenced by the separate discussions of these formulations on page 53 of "Pharmacy Review".

The Examiner is reminded that in order for the doctrine of inherency to be properly applied, it must be demonstrated that the prior art product seems to be identical to the presently claimed invention, except that the prior art is silent as to an inherent characteristic. See MPEP, 8th edition, incorporating Revision No. 1, section 2112. In view of the arguments presented above, it is respectfully submitted that the formulations of the Paradissis reference are different than the formulations recited in the present method claims. Therefore, it is improper for the Examiner to rely on the doctrine of inherency in rejecting the present claims and removal of the anticipation rejection is requested.

C. Rejection Under 35 U.S.C. § 102

In the Office Action, the Examiner maintained her rejection of claims 6-10, 13-16 and 20-23 under 35 U.S.C. § 103(a) as being unpatentable over Paradissis. The Examiner stated that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute hydromorphone or oxycodone for morphine in Paradissis et al. because of the expectation of achieving equivalent pain relief....[or] to exemplify the formulations of Paradissis et al. as comparing at least 50mg of drug because of the expectation of achieving dosage amounts that are effective to treat different levels and forms of pain, and different weight amounts of patients."

In response to the rejection, it is respectfully submitted that even assuming arguendo that one skilled in the art would be motivated to substitute hydromorphone or oxycodone for morphine in the formulations described in the Paradissis reference as asserted by the Examiner, one skilled in the art would arrive at a coated bead formulation and not a matrix formulation as presently claimed. Therefore, the Examiner is respectfully requested to remove the obviousness rejection.

IV. CONCLUSION

A check in the amount of $ 110.00 is enclosed to cover the one-month extension fee. If it is determined that any further fees are due, the Commissioner for Patents is hereby authorized to charge said fees or credit any overpayment to Deposit Account No. 50-0552.

In view of the amendments made and arguments presented, Applicants respectfully submit that the pending claims are in condition for allowance. An early and favorable Action on the merits is earnestly solicited.

Respectfully submitted,
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